Remarks

Claims 1-29 are pending. Claims 3-27 and 29 are withdrawn. Claims 1-2 and 28 are currently under examination.

Claim Rejections – 35 USC § 112

Claims 1, 2, and 28 have been rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabled for a compound of formula (I) or (II) or the pharmaceutically acceptable salt, allegedly does not reasonably provide enablement for a prodrug or metabolite of the compound of formula (I) or (II).

Any analysis of whether a particular claim is enabled by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. The test of enablement is whether one skilled in the art could make or use the claimed invention from the disclosures in the patent coupled with information known in the art without undue experimentation. *United States v. Telectronics, Inc.*, 857 F.2d 778, 8 U.S.P.Q.2d 1217 (Fed. Cir. 1988); *In re Stephens*, 529 F.2d 1343, 199 U.S.P.Q. 659 (CCPA 1976). A patent need not teach, and preferably omits, what is well known in the art. *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 3 U.S.P.Q.2d 1737 (Fed. Cir. 1987). Determining enablement is a question of law based on underlying factual findings. *In re Vaeck*, 947 F.2d 488, 495, 20 U.S.P.Q.2d 1438, 1444 (Fed. Cir. 1991); *Atlas Powder Co. v. E.I. duPont de Nemours & Co.*, 750 F.2d 1569, 224 U.S.P.Q. 409 (Fed. Cir. 1984).

The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *M.I.T. v. A.B. Fortia*, 774 F.2d 1104, 227

U.S.P.Q. 428 (Fed. Cir. 1985). The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt,* 537 F.2d 498, 190 U.S.P.Q. 214 (CCPA 1976).

The standard for use does not change if the subject matter is pharmaceutical or therapeutic in nature. *In re Chilowsky*, 229 F.2d 457, 461-2 (CCPA 1956). "Knowledge of pharmacological activity is an obvious benefit to the public. . . . [A]dequate proof of any such activity constitutes a showing of practical utility" *Nelson v. Bowler*, 626 F.2d 853, 856 (CCPA 1980). The court stated in *In re Brana*, "Usefulness in Patent law and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development." *In re Brana*, 51 F.3d 1560, 1568 (Fed. Cir. 1995). If the subject matter covered by pharmaceutical inventions requires future research and development, even after conception and constructive reduction to practice, when then is the utility requirement met? The Federal Circuit has answered this question: "The stage at which an invention in this field becomes useful [*i.e.* enabled with respect to use requirement] is *well before* it is ready to be administered to humans." (emphasis added). *Id.* at 1568. The prodrugs and metabolites presently claimed are known to those of skill in the art and could have been readily made and tested by one of skill in the art with only routine experimentation. Applicants therefore respectfully request withdrawal of this rejection.

Claim Rejections – 35 USC § 102

Claims 1-2 and 28 have been rejected under 35 U.S.C. 102(e) for allegedly being anticipated by Epstein et al. Applicants respectfully traverse.

A proper rejection of a claim under 35 U.S.C. § 102 requires that a single prior art reference disclose each element of the claim. *See, e.g., W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303, 313 (Fed. Cir. 1983). Anticipation requires that each and every element of the claimed invention be disclosed in a single prior art reference. *See, e.g., In re Paulsen,* 30 F.3d 1475, 31 USPQ2d 1671 (Fed. Cir. 1994); *In re Spada*, 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990). Alternatively, anticipation requires that each and every element of the claimed invention be embodied in a single prior art device or practice. *See, e.g., Minnesota Min. & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.,* 976 F.2d 1559, 24 USPQ2d 1321 (Fed. Cir. 1992). The test is the same for a process. Anticipation requires identity of the claimed process and a process of the prior art. The claimed process, including each step thereof, must have been described or embodied, either expressly or inherently, in a single reference. *See, e.g., Glaverbel S.A. v. Northlake Mkt'g & Supp., Inc.,* 45 F.3d 1550, 33 USPQ2d 1496 (Fed. Cir. 1995). Those elements must either be inherent or disclosed expressly. *See, e.g., Constant v. Advanced Micro-Devices, Inc.,* 848 F.2d 1560, 7 USPQ2d 1057 (Fed. Cir. 1988); *Verdegaal Bros., Inc. v. Union Oil Co.,* 814 F.2d 628, 2 USPQ2d 1051 (Fed. Cir. 1987). Those elements must also be arranged as in the claim. *See, e.g., Richardson v. Suzuki Motor Co.,* 868 F.2d 1226, 9 USPQ2d 1913 (Fed. Cir. 1989); *Carella v. Starlight Archery & Pro Line Co.*, 804 F.2d 135, 231 USPQ 644 (Fed. Cir. 1986). For anticipation, there must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. *See, e.g., Scripps Clinic & Res. Found. v. Genentech, Inc.,* 927 F.2d 1565, 18 USPQ2d 1001 (Fed. Cir. 1991).

Accordingly, the single prior art reference must properly disclose, teach or suggest each element of the claimed invention.

For at least the reason that Epstein et al. fails to disclose, teach, or suggest specifically treating Parkinson's disease, not just memory loss, which is not always a part of Parkinson's disease, Applicants respectfully submit that *Grinvald* does not anticipate Applicants' claims 1-2 and 28. Applicants respectfully request withdrawal of this rejection.

Conclusion

A Credit Card Payment Form PTO-2038 authorizing payment in the amount of $525.00, representing the fee for a small entity under 37 C.F.R. § 1.17(a)(3), and a Request For Extension of Time are enclosed. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

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CERTIFICATE OF EFS-WEB TRANSMISSION UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence, including any items indicated as attached or included, is being transmitted by EFS-WEB on the date indicated below.

/Janell T. Cleveland/
Janell T. Cleveland

December 6, 2007
Date